



1644
C014CIP/DIV2
P/H/C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Not Yet Assigned
Group Art Unit : 1644
Applicants : Michael J. Yellin et al.
Serial No. : 09/342,314
Filed : June 29, 1999
For : THERAPEUTIC APPLICATIONS FOR THE ANTI-T-BAM
(CD40-L) MONOCLONAL ANTIBODY 5c8

RECEIVED

SEP 27 2000

TECH CENTER 1600/2900

New York, New York
September 20, 2000

Hon. Assistant Commissioner
for Patents
Washington, D.C. 20231

TRANSMITTAL LETTER FOR
INFORMATION DISCLOSURE STATEMENT

Sir:

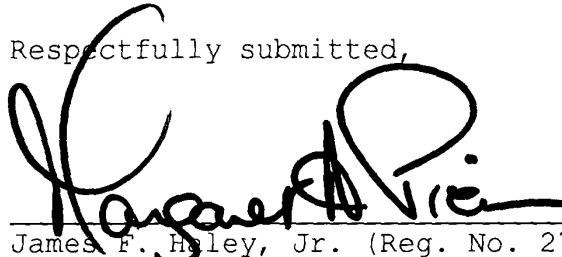
Transmitted herewith is an Information Disclosure
Statement in the above-identified application. This Statement is
submitted:

- ☐ within three months of the application filing date;
- ☒ more than three months from the application filing
date but before the mailing date of the first
Office Action on the merits.

In accordance with 37 C.F.R. § 1.97, submission of this
Statement requires no fee. However, if for any reason a fee is

due, the Commissioner is hereby authorized to charge payment of
any fees required in connection with this
Information Disclosure Statement to Deposit Account No. 06-1075.
A duplicate copy of this letter is transmitted herewith.

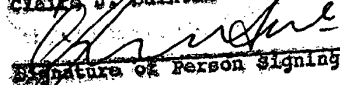
Respectfully submitted,



James F. Haley, Jr. (Reg. No. 27,794)
Margaret A. Pierri (Reg. No. 30,709)
Attorneys for Applicants
c/o FISH & NEAVE
1251 Avenue of the Americas
New York, New York 10020-1104
Tel.: (212) 596-9000

I Hereby Certify that this
Correspondence is being
Deposited with the U.S.
Postal Service as First
Class Mail in an Envelope
Marked for ASSISTANT
COMMISSIONER FOR
PATENTS
WASHINGTON, D.C. 20231 on

September 20, 2000
Clara J. Santilli


Signature of Person Signing



C014CIP/DIV2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Not Yet Assigned
Group : 1644
Applicants : Michael J. Yellin et al.
Serial No. : 09/342,314
Filed : June 29, 1999
For : THERAPEUTIC APPLICATIONS FOR THE ANTI-T-BAM
(CD40-L) MONOCLONAL ANTIBODY 5C8

New York, New York
September 20, 2000

Hon. Assistant Commissioner
for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b) applicants
make of record the following documents:

1. United States patent: 5,474,771
Patentee: Lederman et al.
Issue date: December 12, 1995
2. United States patent: 5,540,926
Patentee: Aruffo et al.
Issue date: July 30, 1996.
3. United States patent: 5,674,492
Patentee: Armitage et al.
Issue date: October 7, 1997.
4. United States patent: 5,677,165

Patentee: de Boer et al.
Issue date: October 14, 1997.

5. United States patent: 5,683,693
Patentee: Noelle et al.
Issue date: November 4, 1997.
6. United States patent: 5,747,037
Patentee: Noelle et al.
Issue date: May 5, 1998.
7. United States patent: 5,833,987
Patentee: Noelle et al.
Issue date: November 10, 1998
8. United States patent 5,869,049
Patentee: Noelle et al.
Issue date: February 9, 1999
9. United States patent 5,876,718
Patentee: Noelle et al.
Issue date: March 2, 1999
10. United States patent 5,876,950
Patentee: Siadak et al.
Issue date: March 2, 1999
11. United States patent 5,902,585
Patentee: Noelle et al.
Issue date: May 11, 1999
12. United States patent 5,916,560
Patentee: Larsen et al.
Issue date: June 29, 1999
13. United States patent 5,942,229
Patentee: Noelle et al.
Issue date: August 24, 1999
14. United States patent 5,945,513
Patentee: Aruffo et al.
Issue date: August 31, 1999
15. United States patent 5,961,974
Patentee: Armitage et al.
Issue date: October 5, 1999
16. United States patent 5,962,406
Patentee: Armitage et al.

Issue date: October 5, 1999

17. United States patent 5,981,724
Patentee: Armitage et al.
Issue date: November 9, 1999
18. United States patent 5,993,816
Patentee: Lederman et al.
Issue date: November 30, 1999
19. United States patent 6,001,358
Patentee: Black et al.
Issue date: December 14, 1999
20. PCT patent application: WO 93/08207
Publication date: April 29, 1993.
21. PCT patent application: WO 93/09812
Publication date: May 27, 1993.
22. PCT patent application: WO 94/04570
Publication date: March 3, 1994.
23. PCT patent application: WO 95/06481
Publication date: March 9, 1995.
24. PCT patent application: WO 95/06666
Publication date: March 9, 1995.
25. PCT patent application: WO 95/09653
Publication date: April 13, 1995.
26. PCT patent application: WO 96/23071
Publication date: August 1, 1996.
27. PCT patent application: WO 96/28568
Publication date: September 19, 1996.
28. PCT patent application: WO 96/40246
Publication date: December 19, 1996.
29. PCT patent application: WO 97/17446
Publication date: May 15, 1997.

Articles

- Alderson, M.R. et al. "CD40 Expression By Human Monocytes: Regulation By Cytokines And Activation Of Monocytes By The Ligand For CD40", *J. Exp. Med.* 178:669-674 (1993).
- Bajorath J. et al. "Identification of Residues on CD40 and Its Ligand Which Are Critical for the Receptor-Ligand Interaction", *Biochemistry* 34:1833-1844 (1995).
- Banchereau J. et al. "The CD40 Antigen and its Ligand", *Annual Rev. Immunol.* 12:881-922 (1994).
- Biancone, L. et al. "Inhibition of the CD40-CD40Ligand Pathway Prevents Murine Membranous Glomerulonephritis", *Kidney Intl.* 48:458-468 (1995).
- Buhlmann, J.E. et al. "Therapeutic Potential For Blockade of the CD40 Ligand, gp39", *J. Clin. Immunol.* 16:83-89 (1996).
- Carbone, A. et al. "Expression of Functional CD40 Antigen on Reed-Sternberg Cells and Hodgkin's Disease Cell Lines", *Blood* 85(3):780-789 (1995).
- Clark, E.A. et al. "Activation of Human B Cells Mediated Through Two Distinct Cell Surface Differentiation Antigens, Bp35 and Bp50", *Proc. Natl. Acad. Sci., USA* 83:4494-4498 (1986).
- Cleary, A. M. et al. "Opposing Roles of CD95 (Fas/APO-1) and CD40 in the Death and Rescue of Human Low Density Tonsillar B Cells", *J. Immunol.* 155:3329-3337 (1995).
- Durie, F.H. et al. "The Role of CD40 and its Ligand (gp39) in Peripheral and Central Tolerance and its Contribution to Autoimmune Disease", *Res. Immunol.* 145:200-205 (1994).
- Durie, F.H. et al. "The Role of CD40 in the Regulation of Humoral and Cell-Mediated Immunity", *Immunol. Today* 15:406-411 (1994).
- Durie, F.H. et al. "Prevention of Collagen-Induced Arthritis With An Antibody to gp39, the Ligand for CD40", *Science* 261:1328-1330 (1993).

- Fanslow W. C. et al. "Soluble Forms of CD40 Inhibit Biologic Responses of Human B Cells", *J. Immunol.* 149:655-660 (1992).
- Freudenthal, P.S. et al. "The Distinct Surface of Human Blood Dendritic Cells, As Observed After An Improved Isolation Method", *Proc. Natl. Acad. Sci., USA* 87:7698-7702 (1990).
- Galy, A.H.M. et al. "CD40 is Functionally Expressed on Human Thymic Epithelial Cells", *J. Immunol.* 149:775-782 (1992).
- Gray, D. et al "Memory B Cell Development But Not Germinal Center Formation is Impaired by In Vivo Blockade of CD40-CD40 Ligand Interaction", *J. Exp. Med.* 180:141-154 (1994).
- Hasbold, J. et al. "Properties of Mouse CD40: Cellular Distribution of CD40 and B Cell Activation by Monoclonal Anti-Mouse CD40 Antibodies", *Eur. J. Of Immunol.* 24:1835-1842 (1994).
- Hollenbaugh, D. et al. "Expression of Functional CD40 by Vascular Endothelial Cells", *J. Exp. Med.* 182:33-40 (1995).
- Karmann, K. et al. "CD40 on Human Endothelial Cells: Inducibility by Cytokines and Functional Regulation of Adhesion Molecule Expression", *Proc. Natl. Acad. Sci., USA* 92:4342-4346 (1995).
- Karpusas, M. et al. "2 Å Crystal Structure of an Extracellular Fragment of Human CD40 Ligand", *Structure* 3(10): 1031-1039 (1995).
- Kuntz, I.D. "Structure-Based Strategies for Drug Design and Discovery", *Science* 257:1078-1082 (1992).
- Kuwana, M. et al. "T and B Cell Collaboration is Essential for the Autoantibody Response to DNA Topoisomerase I in Systemic Sclerosis", *J. Immunol.* 155:2703-2714 (1995).
- Laman, J.D. et al. "The Role of GP39 (CD40 Ligand) in EAE and MS", *J. Neuroimmunology* 54:175 (1994).
- Larsen, C.P. et al. "CD40-gp39 Interactions Play A Critical Role During Allograft Rejection", *Transplantation* 61:4-9 (1996).
- Law, C-L. et al. "Analysis of Expression and Function of CD40 on Normal and Leukemic Human B Cell Precursors", *Leukemia* 4(11):732-738 (1990).

Lederman, S. et al. "The Understanding of Contact-Dependent T-Cell Helper Function in Molecular, Cellular and Physiological Detail", *Res. Immunol.* 145:215-222 (1994).

Mohan, C. et al. "Interaction Between CD40 and Its Ligand gp39 in the Development of Murine Lupus Nephritis", *J. Immunol.* 154:1470-1480 (1995).

Merck Manual of Diagnosis And Therapy, 16th Ed. "Idiopathic Infiltrative Diseases Of The Lungs", Merck Research Laboratories, Rahway, NJ 718-720 (1992).

O'Grady, J.T. et al. "CD40 Expression in Hodgkin's Disease", *Am. J. Of Pathology* 144:(1):2126 (1994).

Paulie, S. et al. "A p50 Surface Antigen Restricted to Human Urinary Bladder Carcinomas and B Lymphocytes", *Cancer Immunol. Immunother.* 20:23-28 (1985).

Potocnik, A.J. et al. "Expression of Activation Antigens on T Cells in Rheumatoid Arthritis Patients", *Scand. J. Immunol.* 31:213-224 (1990).

Stüber, E. et al. "Blocking The CD40L-CD40 Interaction In Vivo Specifically Prevents the Priming of T Helper 1 Cells Through the Inhibition of Interleukin 12 Secretion", *J. Exp. Med.* 183: 693-698 (1996).

Uckun, F.M. et al. "Temporal Association of CD40 Antigen Expression With Discrete Stages of Human B-Cell Ontogeny and the Efficacy Of Anti-CD40 Immunotoxins Against Clonogenic B-Lineage Acute Lymphoblastic Leukemia As Well As B-Lineage Non-Hodgkin's Lymphoma Cells", *Blood* 76(12):2449-2456 (1990).

Urashima, M. et al. "CD40 Ligand Triggered Interleukin-6 Secretion In Multiple Myeloma", *Blood* 85:1903-1912 (1995).

Valent, P. et al. "Further Characterization Of Surface Membrane Structures Expressed On Human Basophils And Mast Cells", *Int. Arch. Allergy Appl. Immunol.* 91:198-203 (1990).

Westendorf, J.J. et al. "Molecular And Biological Role Of CD40 In Multiple Myeloma", *Curr. Top. Microbiol. Immunol.* 194:63-72 (1995).

Westendorf, J.J. et al. "CD40 Expressions In Malignant Plasma Cells", *J. Of Immunol.* 152:117-128 (1994).

Yellin, M.J. et al. "Function of CD40 Molecules Expressed on Cultured Synovial Membrane Fibroblasts" *FASEB J.* (March 10, 1995) 9(4):A774, Abstract No. 4483 - Oral presentation at FASEB Meeting in Atlanta, Georgia" (1995).

Yellin, M.J. et al. "Human Fibroblasts and Endothelial Cells Express CD40 and are Activated by CD40L+ Cells," Poster session at 9th International Congress of Immunology meeting in San Francisco, California (Abstract available July 23, 1995).

Yellin, M.J. et al. "Ligation Of CD40 On Fibroblasts Induces CD54 (ICAM-1) and CD106 (VCAM-1) Upregulation And IL-6 Production And Proliferation," *J. Leukocyte Biology* 58:209-216 (1995).

Yellin, M.J. et al. "Functional Interactions Of T Cells With Endothelial Cells: The Role Of CD40L-CD40-Mediated Signals," *J. Exp. Med.* 182:1857-1864 (1995).

Yellin M. J. et al. "In situ Characterization of CD40L and CD40 Expression in Glomerulonephritis (GN)", Abstract May 1, 1996: ASBMB/ASIP/AAL Joint Meeting.

Yellin M. J. et al. "Function of CD40 Molecules Expressed on Cultured Synovial Membrane Fibroblasts", *FASEB J.* 9:A774 - Abstract No. 4483 (1995).

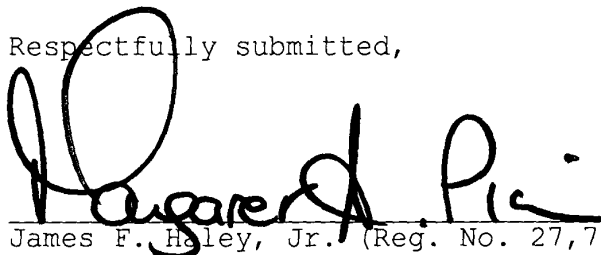
Young, L.S. et al. "Identification Of A Human Epithelial Cell Surface Protein Sharing An Epitope With The C3d/Epstein-Barr Virus Receptor Molecule Of B Lymphocytes," *Int. J. Cancer* 43:786-794 (1989).

For the Examiner's convenience, the above-mentioned documents are listed on the accompanying Form PTO-1449.

Applicants respectfully request that the above-cited documents be (1) fully considered by the Examiner during the continued examination of this application and (2) printed on any patent issuing from this application. Applicants also request that a copy of the enclosed Form PTO-1449, duly initialed by the Examiner, be forwarded to the undersigned with the next communication.

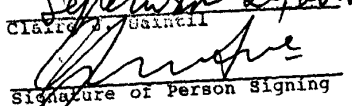
The Commissioner is hereby authorized to charge
payment of any additional fees required in connection with this
Information Disclosure Statement to Deposit Account
No. 061075.

Respectfully submitted,



James F. Haley, Jr. (Reg. No. 27,794)
Margaret A. Pierri (Reg. No. 30,709)
Attorneys for Applicants
c/o FISH & NEAVE
1251 Avenue of the Americas
New York, New York 10020
Tel.: (212) 596-9000
Fax.: (212) 596-9090

I Heroby Certify that this
Correspondence is being
Deposited with the U.S.
Postal Service as First
Class Mail in an Envelope
Addressed to: ASSISTANT
COMMISSIONER FOR
PATENT
WASHINGTON, D.C. 20231 on

September 29, 2000
Claire A. Gairrell

Signature of Person Signing